



*Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)*



HHS SBIR Contract RFP Informational Webinar PHS 2017-1

August 24, 2016

**NIH and CDC SBIR and Contracts Staff
Hosted by Matthew Portnoy
NIH SBIR/STTR Program Coordinator**





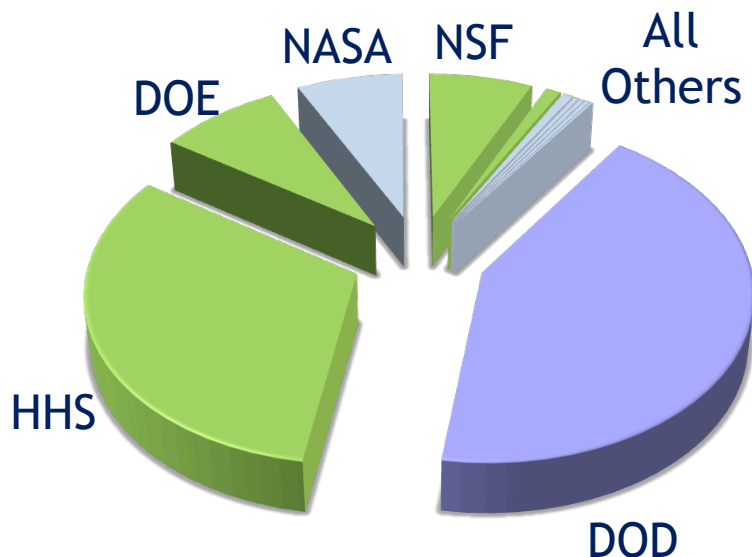
1. **Overview of SBIR and contract RFP**
2. Differences from HHS SBIR grant program
3. Deadlines for Q&A and proposals
4. Electronic proposal submission with eCPS
5. Overview of topics
 - a. NCI
 - b. NCATS
 - c. NHLBI
 - d. NIAID
 - e. NIDA
 - f. CDC





Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SBIR/STTR Budgets by Agency FY2015



~ \$2.5B in FY15
across all agencies

Grants
Contracts



SBIR · STTR
America's Seed Fund

Agencies with SBIR and STTR Programs	Budget
Department of Defense (DOD)	\$ 1.070 B
Department of Health and Human Services (HHS), including the National Institutes of Health (NIH)*	\$797.0 M
Department of Energy (DOE), including Advanced Research Projects Agency - Energy (ARPA-E)	\$206.1M
National Aeronautics and Space Administration (NASA)	\$ 180.1 M
National Science Foundation (NSF)	\$176.0 M
Agencies with SBIR Programs	Budget
U.S. Department of Agriculture (USDA)	\$25.3M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) and Domestic Nuclear Detection Office (DNDO)	\$17.7 M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) and National Institute of Standards and Technology (NIST)*	\$8.4M
Department of Transportation (DOT)	\$7.9 M
Department of Education (ED)	\$7.5 M
Environmental Protection Agency (EPA)	\$4.2 M





Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

HHS Program Funding

2016 Budget	SBIR	STTR
NIH	\$763M	\$114M
CDC	\$9M	N/A
ACL (NIDILRR)	\$2.7M	N/A
FDA	\$1.55M	N/A
ACF	\$93.5K	N/A





Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

NIH SBIR/STTR 3-Phase Program



Discovery

Phase
I

Phase I Feasibility Study

Budget Guide: \$150K for SBIR and STTR

Project Period: 6 months (SBIR); 1 year (STTR)



Development

Phase
II

Phase II Full Research/R&D

\$1M for SBIR and STTR, over two years

Phase
IIB

Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/Tools to FDA
Many, but not all, IC's participate
Varies~\$1M per year; up to 3 years



Commercialization

Phase
III

Phase III Commercialization Stage

NIH, generally, not the “customer”

Consider partnering and exit strategy early



Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

NIH SBIR/STTR Website

U.S. Department of Health & Human Services | National Institutes of Health

OER HOME | ABOUT GRANTS | FUNDING | FORMS & DEADLINES | GRANTS POLICY | ERA | NEWS & EVENTS | ABOUT OER

NIH Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SBIR/STTR HOME
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RESOURCES
STATISTICS AND SUCCESSES
ENGAGE AND CONNECT
New to SBIR/STTR

NIH Technical Assistance Programs
CELEBRATING OVER 11 YEARS
Niche Assessment Program (NAP) | Commercialization Accelerator Program (CAP)

Technical Assistance Programs | Funding | Electronic Submission Process | Success Stories | Contact Us | Engage and Connect

What are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, also known as America's Seed Fund, are one of the largest sources of early-stage capital for technology commercialization in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development that has a strong potential for commercialization.

In Fiscal Year 2016, NIH's SBIR and STTR programs will invest over 870 million dollars into health and life science companies that are creating innovative technologies that align with NIH's mission to improve health and save lives. A key objective is to translate promising technologies to the private sector and enable life-saving innovations to reach consumer markets.

HHS SBIR/STTR COMPONENT PROGRAM LINKS

NEWS

NIH Early Bird Deadline Rapidly Approaching!
Register today for the HHS SBIR/STTR
Conference **NEW**
August 10, 2016

NIH The September 6th SBIR/STTR Deadline is
less than One Month Away
August 9, 2016

<http://sbir.nih.gov>





- NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation
“Parent” FOAs: [SBIR: PA-16-302](#) [STTR: PA-16-303](#)

Release: June 3, 2016

Standard Due Dates: September 5, January 5, April 5

- SBIR Contract Solicitation (NIH, CDC) - Program Solicitation [PHS 2017-1](#) (SBIRs Only)

NIH Guide Notice [NOT-OD-16-123](#)

Release: August 1, 2016 Close: October 21, 2016 (5pm EDT)

- [NIH Guide for Grants and Contracts](#)

Release: Weekly receipt dates specified in each FOA





NIH SBIR site: <https://sbir.nih.gov/funding/phased1>

**R&D Contract
Solicitation:
SBIR Phase I, Fast-Track,
Direct to Phase II
Contract Solicitation,
PHS 2017-1**

Closing Date: October 21, 2016, 5:00PM EDT



PHS 2017-1 (PDF - 1 MB)



PHS 2017-1 (MS Word - 373 KB)



Contract Proposal Forms



NIH OER: Grants & Funding

>> About Grants

>> [Forms Library](#) (Scroll to bottom)

>> Manage a Small Business SBIR/STTR Award

SBIR Contracts

Format	Description	Date Posted	Form/Instruction File
PHS 2017-1	Competing - SBIR Phase I and II Contract Solicitation	August 01, 2016	PDF MS WORD

Receipt date: October 21, 2016, 5PM EDT

Forms for Phase I Proposals:

Appendices:

- A** ([PDF](#) - 88 KB or [MS Word](#) - 31 KB)
- B** ([PDF](#) - 86 KB or [MS Word](#) - 30 KB),
- C** ([PDF](#) - 124 KB or [MS Word](#) - 47 KB),
- F** ([PDF](#) - 94 KB or [MS Word](#) - 26 KB)

Forms for Phase II and Fast-Track Proposals:

Appendices:

- B** ([PDF](#) - 86 KB or [MS Word](#) - 29 KB),
- C** ([PDF](#) - 124 KB or [MS Word](#) - 30 KB),
- D** ([PDF](#) - 90 KB or [MS Word](#) - 31 KB),
- E** ([PDF](#) - 14 KB or [MS Word](#) - 31 KB),
- F** ([PDF](#) - 94 KB or [MS Word](#) - 26 KB),
- G** ([PDF](#) - 265 KB or [MS Word](#) - 35 KB)

Forms for Fast-Track Proposals:

ALL Forms (Appendices A-G) are REQUIRED





FedBizOpps:

[https://www.fbo.gov/spg/HHS/NIH/NIAID/PHS-2017-1/
listing.html](https://www.fbo.gov/spg/HHS/NIH/NIAID/PHS-2017-1/listing.html)

The screenshot displays the FedBizOpps.gov website interface. At the top, the header includes the FedBizOpps.gov logo, the text "Federal Business Opportunities", and navigation links for "Home", "Getting Started", "General Info", "Opportunities", "Agencies", and "Privacy". Below the header, there are links for "Buyers: Login | Register" and "Vendors: Login | Register", along with an "Accessibility" link.

The main content area features a sidebar on the left with the "NATIONAL INSTITUTES OF HEALTH" logo and a "Complete View" section. The central panel displays the title "A SOLICITATION OF THE NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) CONTRACT PROPOSALS". Below the title, it provides the "Solicitation Number: PHS-2017-1", "Agency: Department of Health and Human Services", "Office: National Institutes of Health", and "Location: National Institute of Allergy and Infectious Diseases".

On the right side of the central panel, there are buttons for "Return To Opportunities List", "Watch This Opportunity", and "Add Me To Interested Vendors". Below these, the "Synopsis" section is visible, starting with "Added: Jul 12, 2016 3:17 pm" and followed by a paragraph describing the solicitation. At the bottom of the synopsis, it states: "U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS), THE NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) SMALL BUSINESS".

On the far right, there is a section titled "ALL FILES" containing links for "Solicitation 1" (dated Aug 01, 2016) and "PHS2017-1.pdf". Below this, the "GENERAL INFORMATION" section lists details such as "Notice Type: Solicitation", "Original Posted Date: July 12, 2016", "Posted Date: August 1, 2016", "Response Date: Oct 21, 2016 5:00 pm Eastern", and "Original Response Date: Oct 21, 2016 5:00 pm".





**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), THE
NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR
DISEASE CONTROL AND PREVENTION (CDC) SMALL BUSINESS
INNOVATION RESEARCH (SBIR) PROGRAM**

PROGRAM SOLICITATION PHS 2017-1

Closing Date: October 21, 2016, 5:00 PM Eastern Daylight Time

Participating HHS Components:

- The National Institutes of Health (NIH)
- The Centers for Disease Control and Prevention (CDC)

IMPORTANT

Deadline for Receipt: Proposals must be received by October 21, 2016, 5:00 PM Eastern Daylight Time.

Please read the entire solicitation carefully prior to submitting your proposal.

IMPORTANT: All proposals must be submitted using the electronic contract proposal submission (eCPS) website.

Paper proposals will not be accepted.

Please go to https://www.sbir.gov/sites/default/files/sbir_pd_with_1-8-14_amendments_2-24-14.pdf to read the SBIR/STTR Policy Directive issued by the Small Business Administration for further information.





- 1 INTRODUCTION
- 2 PROGRAM DESCRIPTION
- 3 DEFINITIONS
- 4 PROPOSAL FUNDAMENTALS
- 5 CONTRACT REQUIREMENTS
- 6 METHOD OF EVALUATION
- 7 PROPOSAL SUBMISSION
- 8 PROPOSAL PREPARATION AND INSTRUCTIONS
- 9 HHS COMPONENTS ANTICIPATED NUMBER OF AWARDS
- 10 CONTRACTING OFFICER POINTS OF CONTACT
- 11 SCIENTIFIC AND TECHNICAL INFORMATION SOURCES
- 12 COMPONENT INSTRUCTIONS AND TECHNICAL TOPIC DESCRIPTIONS



Read the entire RFP several times!!



- National Institutes of Health (NIH):
 - NCI NCATS NIAID
 - NHLBI NIDA
- Centers for Disease Control and Prevention (CDC):
 - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
 - National Center for Emerging Zoonotic and Infectious Diseases (NCEZID)



Types of SBIR Proposals Allowed Section 1 and 12

TOPIC NUMBER	PHASE I PROPOSAL ALLOWED ? (INCLUDES ONLY A PHASE I PROPOSAL)	FAST TRACK PROPOSAL ALLOWED ? (INCLUDES A PHASE I PROPOSAL AND A PHASE II PROPOSAL)	DIRECT TO PHASE II ALLOWED ? (INCLUDES ONLY A PHASE II PROPOSAL)	TOPIC TITLE
NIH/NCI 355	Yes	Yes	Yes	Cell and Animal-Based Models to Advance Cancer Health Disparity Research
NIH/NCI 356	Yes	No	No	Tools and Technologies for Monitoring RNA
NIH/NCI 357	Yes	Yes	Yes	Innovative Tools for Interrogating Tumor Microenvironment Dynamics
NIH/NCI 358	Yes	No	No	Modulating the Microbiome to Improve Therapeutic Efficacy of Cancer Therapeutics





What is a complete Phase I submission? Section 8.3

TECHNICAL PROPOSAL (1 PDF)

- Item 1: Technical Element
- Proposal Cover Sheet Appendix A
- Table of Contents
- Abstract of the Research Plan, (Appendix B)
- Content of the Technical Element
- Summary of Related Activities (Appendix F)

BUSINESS PROPOSAL (1 PDF)

- Item 2: Pricing Proposal (Appendix C)
- Item 3: SBIR Application VCOC Certification, if applicable
- Item 4: Proof of Registration in the SBA Company Registry





What is a complete Phase II submission? Section 8.4

TECHNICAL PROPOSAL (1 PDF)

- Item 1: Technical Element
- Technical Proposal Cover Sheet Appendix D
- Table of Contents
- Abstract of the Research Plan, (Appendix B)
- Content of the Technical Element
- Draft Statement of Work (Appendix E)
- Summary of Related Activities (Appendix F)
- Proposal Summary and Data Record (Appendix G)

• BUSINESS PROPOSAL (1 PDF)

- Item 2: Pricing Proposal (Appendix C)
- Item 3: SBIR Application VCOC Certification, if applicable
- Item 4: Proof of Reg. in the SBA Company Registry





Human Subjects or Vertebrate Animal Work?

- Section 3 - Definitions
- Section 4.9 - Research Involving Human Subjects
- Section 4.10 - Inclusion of Women, Minorities, and Children in Clinical Research
- Section 4.11 - Care of Vertebrate Animals
- Section 8.10 - Human Subjects Research and Protection from Risk Instructions
- Section 8.11 - Inclusion of Women, Minorities, and Children in Clinical Research Instructions
- Section 8.12 - PHS Inclusion Enrollment Report(s) for Sex/Gender, Race, and Ethnicity
- Section 8.13 - Research Involving Human Fetal Tissue Instructions
- Section 8.14 - Research Involving Vertebrate Animals Instructions



- New this year NIH-wide
- Section 8.9 - Enhancing Reproducibility through Rigor and Transparency
- [NOT-OD-15-103](#): View overall NIH Guidance
 - >> Specific instructions in Section 8.9



- **SBIR Phase I** technical proposals (Item 1) shall not exceed 50 pages
- **SBIR Phase II** technical proposals (Item 1) shall not exceed 150 pages
- **Fast Track** = a complete Phase I + a complete Phase II
- Single-sided, single-spaced pages for entire proposal
- All inclusive [including all pages, cover sheet(s), tables, CVs, resumes, references, pictures/graphics, and all enclosures, appendices or attachments, etc.]
- No exclusions to page limits. Pages in excess of the page limitation will be removed from the proposal and will not be considered or evaluated



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Differences between SBIR Contracts and Grants

Contracts	Grants
Acquisition mechanism	Assistance mechanism
Follows FAR and SBIR Policy Directive	Follows Grants Policy and SBIR Policy Directive
NOT Investigator Initiated	Investigator Initiated
Narrow, well defined topics	Broad or narrow topics
RFP: Offeror: Contractor: Proposal	PA, PAR, RFA: Applicant: Grantee: Application
Only contact is Contracting Officer	Call Program Officer anytime for anything
eCPS - New (used to be on paper)	SF424, grants.gov, eRA Commons



Differences between SBIR Contracts and Grants

Need to use for Contract?	
SBIR Company Registry	Yes - for all offerors
VCOC Certification	Yes - if applicable
DUNS	Yes
SAM	Yes - (at time of award)
Grants.gov	No
eRA Commons	No - (can use to reg in eCPS)
Electronic Contact Proposal Submission (eCPS)	Yes - required to submit all proposals to PHS 2017-1



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- Reminder only contact is with Contracting Officer listed in Section 10
- Questions must be submitted in writing (email) to the Contracting Officer
- **Deadline for Questions is September 1, 2016 - close of business**
- An Q&A amendment will be issued in ~ mid September in FBO and on NIH SBIR websites
 - **Yes, your questions and the answers will be posted to the public**
- Additional questions will be answered at the discretion of the CO





*Small Business Innovation Research (SBIR)
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Deadline for receipt of ALL Proposals

FRIDAY October 21, 2016

5:00 PM Eastern Daylight Time

Electronic submission must be complete.

No paper submissions.





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- **REQUIRED for ALL PROPOSALS**
- Paper proposals no longer accepted
- Section 7.4 Submission, Modifications, Revision, and Withdrawal of Proposal

electronic Contract Proposal Submission (eCPS)

<https://ecps.nih.gov/sbirsttr>



Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

eCPS Demo

eCPS live demo!





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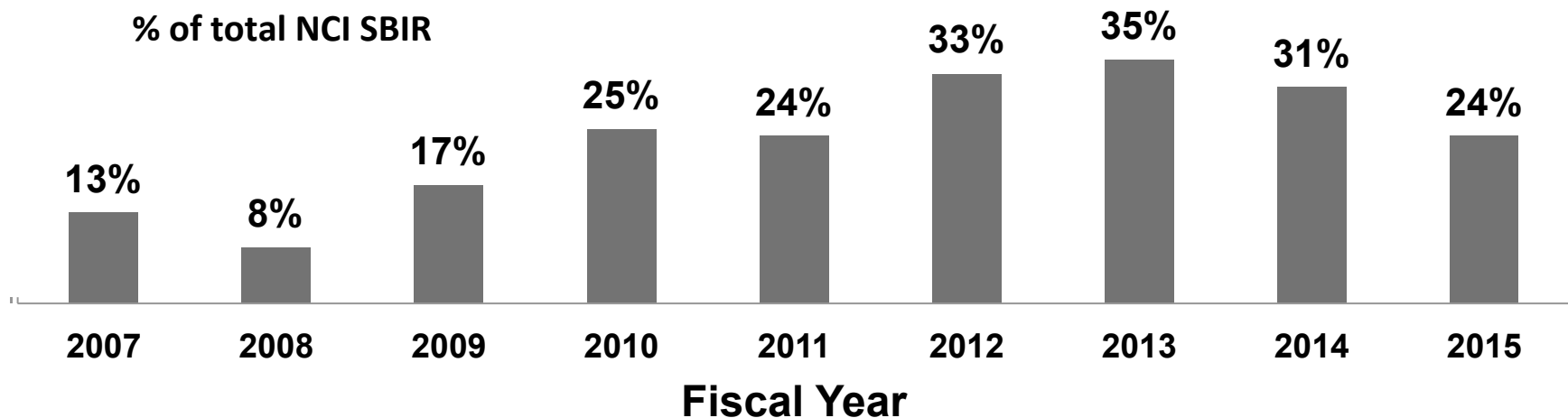
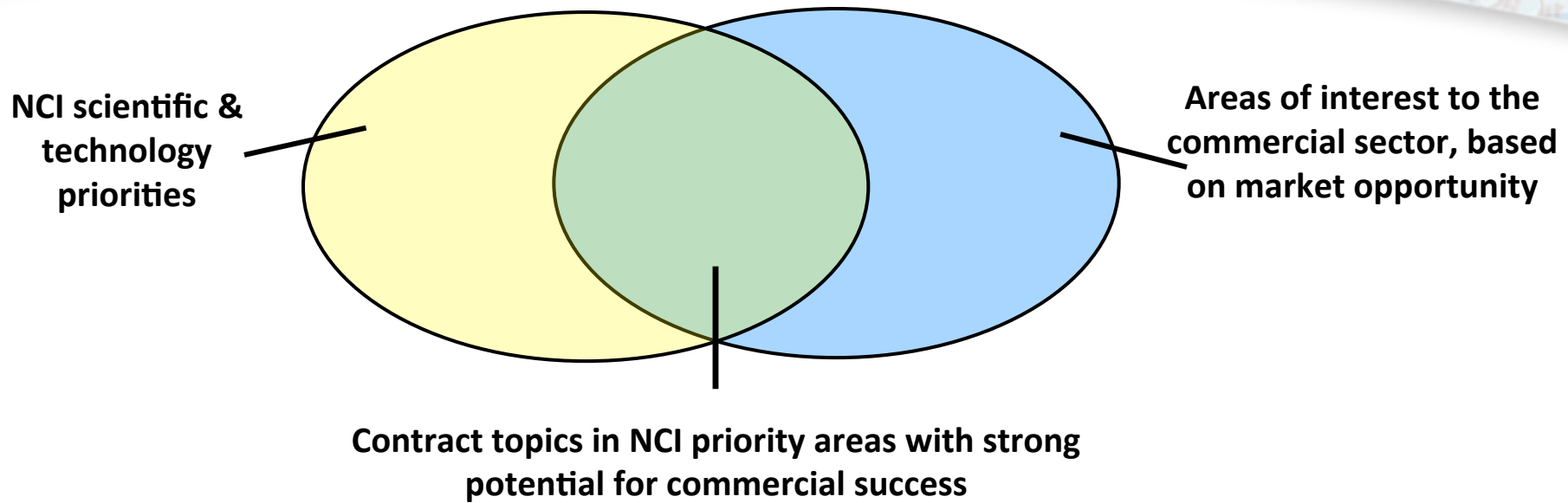


NCI SBIR Contract Funding Opportunities

<http://sbir.cancer.gov/funding/contracts>



Annual Solicitation for NCI SBIR Contract Topics



NCI Contract Topics for FY2017



<http://sbir.cancer.gov/funding/contracts>

15 topics in FY2017 Solicitation

- **NIH/NCI 355**: Cell and Animal-Based Models to Advance Cancer Health Disparity Research
- **NIH/NCI 356**: Tools and Technologies for Monitoring RNA
- **NIH/NCI 357**: Innovative Tools for Interrogating Tumor Microenvironment Dynamics
- **NIH/NCI 358**: Modulating the Microbiome to Improve Therapeutic Efficacy of Cancer Therapeutics
- **NIH/NCI 359**: Technologies for Differential Isolation of Exosomes and Oncosomes
- **NIH/NCI 360**: Manufacturing Innovation for the Production of Cell-Based Cancer Immunotherapies
- **NIH/NCI 361**: Highly Innovative Tools for Quantifying Redox Effector Dynamics in Cancer
- **NIH/NCI 362**: Informatics Tools to Measure Cancer Care Coordination
- **NIH/NCI 363**: Connecting Cancer Caregivers to Care Teams: Digital Platforms to Support Informal Cancer Caregiving
- **NIH/NCI 364**: Methods and Software for Integration of Cancer Metabolomic Data with Other –Omic and Imaging Data
- **NIH/NCI 365**: Imaging Informatics Tools and Resources for Clinical Cancer Research
- **NIH/NCI 366**: Clonogenic High-Throughput Assay for Screening Anti-Cancer Agents and Radiation Modulators
- **NIH/NCI 367**: Predictive Biomarkers to Improve Radiation Treatment
- **NIH/NCI 368**: Molecularly Targeted Radiation Therapy for Cancer Treatment
- **NIH/NCI 369**: Development of Pediatric Cancer Drug Delivery Devices

Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals will be accepted.

Direct-to-Phase II will be accepted.

Goal: Develop new, commercially available models relevant to diverse racial/ethnic populations. These models may be used to enhance research capabilities of basic scientists and/or provide novel tools to pharmaceutical companies for preclinical oncology studies. Solicited Models include:

- Cancer Cell Lines
- PDX Mouse Models
- 3D Human Tissue Model Culture Systems

Phase I Activities & Deliverables Include:

- Cancer Cell Lines: Establish a stable cell line from human tumor cells and passage the cells in culture to determine viability and experimental relevance.
- PDX Animal Models: Establish a serially transplantable, phenotypically stable, human cancer xenograft model in immunocompromised mice.
- 3D human tissue model culture system: Establish a 3D culture that mimics the tumor microenvironment. Note that proposed model systems must be using established technologies with previously demonstrated reproducibility in pre-clinical or chemo-sensitivity assays.

Budget: Phase I \$250,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 3-5

Fast-Track proposals will not be accepted.

Direct-to-Phase II will not be accepted.

Goal: To incentivize small businesses to generate tools, technologies, and products for monitoring covalently modified eukaryotic RNA, including messenger RNA and regulatory RNA.

Phase I Activities & Deliverables Include:

- Identify and justify development of a tool or technology for monitoring a specific RNA modification or set of RNA modifications.
- Describe the current state of the art technologies, if any, for monitoring the specific RNA Modification(s) and outline the advantages that their approach will provide.
- Develop and characterize the tool or technology for monitoring the specific RNA Modification(s).
- Specify and justify quantitative milestones that can be used to evaluate the success of the tool or technology being developed.
- Develop an assay or system for testing and benchmarking the specificity and sensitivity of the tool or technology and comparing the tool or technology to existing approaches if applicable.
- Provide a proof-of-concept SOP for the tool or technology.

Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 3-5

Fast-Track proposals accepted.

Direct-to-Phase II proposals accepted.

Goal: Develop non-invasive, in vivo platforms that can: image, assess or interrogate TME dynamics over time for tumor diagnosis and/or treatment prediction/response.

Phase I Activities & Deliverables Include:

- Identification and validation of marker(s) for TME
- Prepare, select and demonstrate TME-targeting probes/sensors based on target specificity and minimal toxicity in vitro
- Optimize detection scheme to demonstrate in vitro signal specificity and correlate signals to molecular target concentrations measured using conventional assays
- Determine optimal dose and detection window through proof-of-concept small animal studies with evidence of systemic stability and minimal toxicity
- Establish calibration curves correlating in vivo signal changes to concentration of molecular targets measured via conventional biological assays.
- Demonstrate robust signal changes in response to in vivo perturbation
- Benchmark experiments against currently state-of-the-art methodologies.

NIH/NCI 358: Modulating the Microbiome to Improve Therapeutic Efficacy of Cancer Therapeutics



Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 2-4

Fast-Track proposals not accepted.

Direct-to-Phase II proposals not accepted.

Goal: Develop effective adjuvant strategies that specifically target critical microbial activities or populations that affect drug efficacy and/or tolerability.

Phase I Activities & Deliverables Include:

- Define and characterize a host/microbe interaction that affects therapeutic efficacy, demonstrated through appropriate in vitro and in vivo experiments.
- Develop targeted microbiota regulated/directed intervention strategies designed to improve, either alone or in combination, patient outcomes for new or current therapeutic agents
- Test and refine therapeutic approaches in order to identify lead candidates or agent to develop further in Phase II studies
- Offeror should determine and justify the assays and endpoints that will be used to evaluate the success of their approach.
- Submit a statement to NCI that specifies the metrics and criteria used to evaluate the success of the approach being developed, and justification for these metrics and criteria from a commercial and scientific perspective.

Budget: Phase I \$300,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals not accepted.

Direct-to-Phase II proposals not accepted.

Goal: Accelerate the use of exosomes from body fluids for cancer research and clinical care, and Develop technology for differential isolation of tissue-specific exosomes and oncosomes in serial collections of archived body fluids to enable assessment of cancer initiation, progression, risk, aggressiveness, prognosis and/or treatment outcomes.

Phase I Activities & Deliverables Include:

- Develop a technology for differential isolation of exosomes and oncosomes, which originated in a specific tissue, from body fluid(s) collected from cancer patients.
- Demonstrate that the technology can obtain distinct preparations of exosomes and oncosomes from the routinely collected fresh/archived body fluids, and yields sufficient quantity for downstream analysis.
- Demonstrate that the reproducibility is >90% and yield is >70%
- Demonstrate collection of >75% intact and undamaged exosomes/oncosomes is using physicochemical methods.
- Deliver to NCI the SOPs for exosome/oncosome isolation, and the data from physicochemical characterization that demonstrates the quality

Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 2-4

Fast-Track proposals accepted.

Direct-to-Phase II proposals not accepted.

Goal: Facilitate the development of innovative methods and technologies capable of improving and modernizing product manufacturing processes for cell-based cancer immunotherapies.

Phase I Activities & Deliverables Include:

- Develop a device/technology/process to support commercially-relevant manufacturing advancements or improvements for the production of a specific class of cell-based cancer immunotherapies
- Provide proof of collaboration or partnership with an entity that is developing a representative cell-based therapeutic agent OR otherwise demonstrate access to a representative cell-based therapeutic agent through other means that can be used for validation of the device/technology/process
- Demonstrate pilot-scale beta-testing of the production process to demonstrate reproducible performance within appropriate specifications for identity, purity, potency, and/or other relevant metric for the chosen cell-based immunotherapy product

NIH/NCI 361: Highly Innovative Tools for Quantifying Redox Effector Dynamics in Cancer



Budget: Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 2-4

Fast-Track proposals not accepted.

Direct-to-Phase II proposals not accepted.

Goal: Develop quantitative tools to measure redox dynamics in biological systems. Ideally, probes or biosensor tools should be minimally invasive as to not significantly perturb the system. The technical approach should:

- (1) allow for in vivo measurements of redox effector spatiotemporal dynamics; and/or
- (2) be useable in high throughput systems.

Phase I Activities & Deliverables Include:

- Identify and justify development of a sensing tool or probe for specific redox effector species from both a cancer biology and commercial perspective.
- Develop and characterize a redox probe, biosensor or detection platform. Offerors shall specify quantitative milestones that can be used to evaluate the success of the technology being developed, and justify these milestones from the viewpoint of both scientific utility and commercial value.
- Develop an assay or system that demonstrates proof-of-concept testing and benchmarking of specificity and sensitivity parameters of the agent or system for a range of redox effector species.

NIH/NCI 362: Informatics Tools to Measure Cancer Care Coordination



Budget: Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals accepted.

Direct-to-Phase II proposals not accepted.

Goal: Create scalable health IT-based informatics tools that measure care coordination in order to assess and improve quality of care and patient outcomes, assist the ongoing healthcare delivery system transformation and improve research efficiency.

Phase I Activities & Deliverables Include:

- Develop a prototype platform to generate at least 5 cancer-relevant care coordination measures from EHRs and other relevant, IT platforms at one cancer care delivery site and to display them in the right format to the right user at the right time.
- Develop a prototype platform to assess clinical team composition; workflows and team interactions with health IT; flow of relevant data across diverse delivery sites; extent of patient engagement; type of health IT implementation, and organizational structure and policies relevant to the informatics tool development and implementation at one cancer care delivery site.
- Provide a report detailing plans for implementation of technical assistance and delivery of software, platform, and measures developed.

NIH/NCI 363: Connecting Cancer Caregivers to Care Teams: Digital Platforms to Support Informal Cancer Caregiving



Budget: Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals accepted.

Direct-to-Phase II proposals not accepted.

Goal: Develop software, database systems and mobile application tools to support cancer caregivers and connect them with their patients' care teams.

Phase I Activities & Deliverables Include:

- Establish a project team with expertise in the areas of software development, patient-centered design, health communication, oncology, oncology nursing, palliative care, family medicine behavioral science, health services, and computer programming. Note that team members may have dual expertise
- Perform an environmental scan of available and relevant software systems designed to support cancer patients and caregivers to identify major gaps
- Conduct a small number of key informant interviews with cancer patients and caregivers to further refine and prioritize areas of unmet needs
- A dashboard/database that would communicate to caregivers, patients, and providers about community resources
- Develop a functional prototype of the software system

Budget: Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals accepted.

Direct-to-Phase II proposals not accepted.

Goal: Develop new and innovative bioinformatic methods to integrate metabolite data with and other –omics and/or cancer imaging data and ultimately design scalable software tool(s) that apply these methods to automate the integration of the data.

Phase I Activities & Deliverables Include:

- Develop bioinformatic methods for identified metabolite data integration with other –omics and/or cancer imaging data for at least one analytical technology used in metabolomics and at least one analytical technology used in in genomics, proteomics, epigenomics, transcriptomics, or cancer imaging. Datasets with cancer outcomes must be used.
- Develop data formats that support the import and export of individual datasets and “combined” datasets, store structured data from different sources of metabolite and other –omics and/or cancer imaging data, and are readily used for data integration and QC protocols.
- Finalize data formats and structure, data collection, transport and importation methods for targeted Phase I data inputs.

Budget: Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals accepted.

Direct-to-Phase II proposals not accepted.

Goal: Develop and implement solutions for sustained support for the advanced development, evolution, and broad adoption of cancer imaging informatics tools and resources.

Phase I Activities & Deliverables Include:

- Design specifications for enhancing image informatics tools and resources to support required usability, data and tools interoperability, patient data protection, as well as other features required for supporting phase II commercialization,
- Clear documentation of the tools and resources, and
- An early phase product prototype and detailed project plan for phase II implementation, as well as a demonstration of the prototype to NCI (using funds set aside for this purpose).

NIH/NCI 366: Clonogenic High-Throughput Assay for Screening Anti-Cancer Agents and Radiation Modulators



Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 3-5

Fast-Track proposals not accepted.

Direct-to-Phase II proposals not accepted.

Goal:

- (i) Promote stronger academic industry partnerships in radiobiology to develop clonogenic survival-based HTS systems
- (ii) Exploit recent advances in the technical maturity of HTS technologies and combine them with advances in clonogenic assays
- (iii) Encourage small businesses to specifically develop HTS systems for screening potential anti-cancer agents based on a clonogenic endpoint
- (iv) Integrate relevant technologies.

Phase I Activities & Deliverables Include:

- Delivery of a prototype system with validated SOPs that are translatable to other laboratories.
- Defined cell line panels that have been shown to be appropriate for use with the system and the clonogenic endpoint. Validation of representative “hits” using conventional clonogenic assay.
- Licensing of individual components for use in the system as needed.

Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals accepted.

Direct-to-Phase II proposals not accepted.

Goal: Develop a simple cost effective test that can be used by clinicians to personalize radiation/chemoradiotherapy treatment regimens.

Phase I Activities & Deliverables Include:

- Discovery and early development
 - Demonstrate biomarker prevalence and utility
 - Develop a working qualitative test correlating the presence or absence of the biomarker(s) with potential outcome or a quantitative assay to assess radiation sensitivity
 - Demonstrate feasibility
- Preclinical development and technical validity
 - Provide assay characteristics
 - Illustrate the performance of the biomarker(s) with receiver operating characteristic (ROC) data
 - Demonstrate suitability of the test for use in the clinic, including kinetics of biomarker, if transient.

Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals accepted.

Direct-to-Phase II proposals not accepted.

Goal:

- Short-term goal - to perform feasibility studies for development and use of possible radiotherapeutics for the treatment of cancer.
- Long-term goal - to enable a small business to bring a fully developed TRT compound or TRT-supporting technology to the clinic and eventually to the market.

Phase I Activities & Deliverables Include:

- Proof-of-concept of the conjugation or attachment of the radioisotope to the antibody or other targeting moiety.
- Radiation dosimetry studies in an appropriate small animal model
- Proof-of-concept small animal studies demonstrating an improved therapeutic efficacy and improved therapeutic index, assessment of toxicity to normal tissues, and pharmacokinetic/pharmacodynamic studies utilizing an appropriate animal model.

NIH/NCI 369: Development of Pediatric Cancer Drug Delivery Devices



Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 2-4

Fast-Track proposals accepted.

Direct-to-Phase II proposals not accepted.

Goal: Develop technologies to aid the administration of cancer therapies to pediatric patients, taking into account pediatric specific issues which include but are not limited to: dosage limitations, size restraints, comfort level and mobility.

Phase I Activities & Deliverables Include:

- Select cancer type(s), site(s) and cancer drugs for the development of delivery device with adequate justification
- Design and develop a prototype of a drug delivery device that is
- Suitable for the anatomical restrictions of pediatric patients.
- Suitable for the dosage limitations of pediatric patients.
- Demonstrate preliminary proof-of-concept of the device in a suitable animal model.
- Develop the required specifications necessary to make the device clinic ready.
- Demonstrate understanding of the requirements to file a regulatory application for the device

Questions About NCI SBIR Contracts?

Ms. Tiffany Chadwick

ncioasbir@mail.nih.gov

Please reference solicitation PHS 2017-1 and the Topic number with any questions.

<http://sbir.cancer.gov/funding/contracts/>

NCATS: Development of a Drone to be used in Laboratory Automation Projects

Summary and Background: Currently, there are many options for robots in the space of laboratory automation, especially in the area of High Throughput Screening (HTS). These robotic arms bring tremendous benefit to a HTS environment; however, they are not without limitation. Some of the limitations of these robotic systems are the cost, the safety requirements, the work envelope and the expertise required to operate/repair them. By using low cost commercially available drones and open source software the realm of fully automated laboratory operations could become more accessible to facilities not currently equipped or funded to do so.

Project Goals: The purpose of this contract proposal is to create an indoor autonomous drone capable of moving commonly used industry standard SLAS footprint Microplates from one location to another. Expected series of events:

- The drone takes off from a base station
- The drone flies to the pick-up location to pick up a microplate
- The drone actuates a gripping mechanism of some sort to pick the microplate up
- The drone flies along a predetermined (or adaptive) flight path to the drop-off location
- The drone drops the microplate off at the drop-off location
- The drone returns to the base station
- This process should be able to repeat without interruption 24 hours per day

Contract Specifics:

- Fast-Track proposals will **not** be accepted.
- Phase II information is provided only for informational purposes to assist
- Phase I offerors with their long-term strategic planning.
- Anticipated awards: 1-2
- Budget (total costs, per award):
- Phase I: \$225,000 for 9 months
- Phase II: \$1,500,000 for 2 years

Contract Topics for the National Heart, Lung, and Blood Institute (NHLBI)

Questions? Contact:

John Taylor

taylorjc@nhlbi.nih.gov

Full details of NHLBI topics:

<http://bit.ly/FY17HLcontracts>



Find resources and additional funding opportunities

<http://www.nhlbi.nih.gov/sbir>



National Heart, Lung,
and Blood Institute

NHLBI 098 Testing & Validation of Technologies for Inclusion in the CART Demonstration Product for Collaborative Aging Research

■ **Project Goals**

- Develop research evidence to support the use of technologies in the home that address heart, lung, blood, or sleep diseases using the Collaborative Aging (in Place) Research Using Technology (CART) research infrastructure.

■ **Phase I Activities and Expected Deliverables**

- Working prototype ready for formal validation with minimal further development other than that required to perform the validation or outcomes research
- Process for installing and monitoring the technology installed for CART homes
- Documentation that the product to be evaluated has been developed based on theory and/or empirical evidence
- Appropriate focus groups, interviews, cognitive or user testing with potential end-users of the device/software tool, etc. conducted to demonstrate feasibility, acceptability, and usability of the product

■ **Phase II Activities and Expected Deliverables**

- IT customization to support hardware, software, or communications system integration of the technology into the target clinical setting, health system or service, or other relevant software environment in preparation for validation, according to the CART specifications. The CART specifications will be developed within a year of the CART RFA award and will require collaboration with the small business partner awarded a contract.
- Test the integration of the technology into the target clinical setting, health system or service, or other relevant software environment in preparation for validation.
- Develop user support documentation to support all applicable potential users of the technology, including but not limited to patients/consumers, family/caregivers, and providers.

Budget (total costs)

Phase I: up to **\$150,000**

for up to 6 months

Phase II: up to **\$1,000,000**

for up to 24 months

Only Fast-Track or Direct-to-Phase II proposals will be accepted.

Anticipated awards: 3

NHLBI 099 Inhalational 5A Apolipoprotein A-I Mimetic Peptide for the Treatment of Asthma (SBIR-Technology Transfer)

■ **Project Goals**

- Development of an inhalational formulation of the 5A apolipoprotein A-I (apoA-I) mimetic peptide for treatment of severe asthma.

■ **Phase I Activities and Expected Deliverables**

- Demonstrate that a comparable 5A apoA-I mimetic peptide can be synthesized and attenuate allergen-induced airway inflammation when administered by a pulmonary route in a pre-clinical asthma model.
- Synthesis of a non-GMP grade 5A apoA-I mimetic peptide for comparability studies
- Dose ranging animal studies to reproduce previous preclinical results

■ **Phase II Activities and Expected Deliverables**

- Develop an inhaled formulation of the 5A apoA-I mimetic peptide for use in human clinical trials.
- Stability testing of the inhaled formulation of the 5A apoA-I mimetic peptide and early pre-clinical animal studies.

- Contractors funded under this SBIR-TT topic will automatically be granted a royalty-free, non-exclusive license to make and use, but not to sell or offer to sell, for background inventions covered by the NIH-owned patent rights. Offerors/contractors can apply for an exclusive or non-exclusive commercialization license.

- Contractor(s) funded under this topic will work closely with the NHLBI inventor(s), who will assist in preclinical experiments and will perform a clinical trial using the offeror's product.

- Offerors are encouraged to consider the NHLBI Phase IIB Bridge or Small Market Award grant programs to support additional development beyond Phase II.

Budget (total costs)

Phase I: up to **\$225,000**

for up to 12 months

Phase II: up to **\$1,500,000**

for up to 24 months

Fast-Track proposals **will** be accepted. Direct-to-Phase II proposals **will not** be accepted.

Anticipated awards: 2

Issued Patents:

[NIH Reference Number E-114-2004/0](#)

(<https://www.ott.nih.gov/technology/e-114-2004>)

NHLBI 100 MRI Myocardial Needle Chemoablation Catheter

■ **Project Goals**

- Development and testing of an endomyocardial injection needle chemoablation catheter that is safe for operation during MRI, to allow targeted myocardial delivery of caustic agents.

■ **Phase I Activities and Expected Deliverables**

- Development and testing of a myocardial injection needle prototype
- Detailed report of pre-submission interactions with the FDA Center for Devices and Radiological Health (CDRH) identifying requirements for Investigational Device Exemption (IDE) development under Phase II

■ **Phase II Activities and Expected Deliverables**

- Mechanical and safety testing and regulatory development for the device to be used in human investigation, whether under Investigational Device Exemption (IDE) or under 510(k) marketing clearance.
- Deliverable is IDE license or 510(k) clearance, along with twenty clinical investigational prototypes.

- NHLBI is willing to provide feedback about design at all stages of development, and will test the final deliverable device for success in vivo in swine. This requires specific hardware compatibility with the NIH Siemens Aera 1.5T MRI system.
- NHLBI offers to perform an IDE clinical trial at no cost to the awardee.

Budget (total costs)

Phase I: up to **\$300,000**

for up to 18 months

Phase II: up to **\$2,000,000**

for up to 24 months

Fast-Track and Direct-to-Phase II proposals **will** be accepted.

Anticipated awards: 1

NHLBI 101 Membranous Ventricular Septal Defect (pmVSD) Transcatheter Occluder System

■ **Project Goals**

- Development of a device for percutaneous closure of membranous VSD in infants and children, with an acceptable low rate of complete heart block compared with surgical closure.

■ **Phase I Activities and Expected Deliverables**

- Development and testing of a pmVSD occluder prototype suitable for children and newborn infants
- Pre-submission interactions with the FDA Center for Devices and Radiological Health (CDRH), indicating a sufficiently mature device and identifying requirements for Investigational Device Exemption (IDE) development under Phase II

■ **Phase II Activities and Expected Deliverables**

- Mechanical and safety testing and regulatory development for the device to be used in human investigation
- Activities in Phase II should align with the required testing and development milestones agreed upon with the FDA in Phase I.
- Deliverable is complete IDE documentation and license and a suitable supply of clinical materials

- NHLBI offers, but does not require, to test a final prototype in vivo, perform the clinical trial at no expense to the offeror, to participate in the development of the clinical protocol, and to provide clinical research services.

Budget (total costs)

Phase I: up to **\$400,000**

for up to 21 months

Phase II: up to **\$3,000,000**

for up to 36 months

Fast-Track and Direct-to-Phase II proposals **will** be accepted.

Anticipated awards: 1

NHLBI 102 Transcatheter Occluder Device for Paravalvular Leaks

■ **Project Goals**

- Development of a device for percutaneous closure of paravalvular leak

■ **Phase I Activities and Expected Deliverables**

- Development and testing of a catheter system for implantation of a paravalvular leak occluder.
- Detailed report of pre-submission interactions with the FDA Center for Devices and Radiological Health (CDRH), indicating a sufficiently mature device and identifying requirements for Investigational Device Exemption (IDE) development under Phase II
- A final prototype with phantom testing

■ **Phase II Activities and Expected Deliverables**

- Mechanical and safety testing and regulatory development for the device to be used in human investigation
 - Activities in Phase II should align with the required testing and development milestones agreed upon with the FDA in Phase I.
 - Deliverable is complete IDE documentation and license and a suitable supply of clinical materials would constitute the final deliverable. For all purposes, a humanitarian device exemption (HDE) or an expedited Premarket Approval (PMA) would be considered responsive in place of IDE.
- NHLBI offers, but does not require, to perform the clinical trial at no cost to the awardee.

Budget (total costs)

Phase I: up to **\$400,000**
for up to 21 months

Phase II: up to
\$3,000,000 for up to 36
months

Fast-Track and Direct-to-
Phase II proposals **will**
be accepted.

Anticipated awards: 1



*Small Business Innovation Research (SBIR)
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**SBIR Contract solicitation PHS 2017-1
NIAID topics**

**Dr. Wolfgang Leitner
Chief of the Innate Immunity Section Basic
Immunology Branch (BIB)
Allergy, Immunology, and Transplantation
Division, NIAID**





SBIR Contract solicitation PHS 2017-1 contains opportunities to submit a proposal under a variety of different **NIAID topics**

- **040 Effective Targeted Delivery of RNA-based Vaccines and Therapeutics**
- **041 Simplified Sequencing for TB Drug Resistance Testing**
- **042 Qualitative HIV RNA Home Test**
- **043 Adjuvant Development**
- **044 Vaccine Adjuvant Screening and Discovery**
- **045 Database Resources Integration**
- **046 Rapid Point-of-Care Diagnostics to Detect Serologic Status of Individuals for Select Viral Infections**
- **047 Development of Microbiome-based Products for Infectious Diseases**
- **048 Non-Invasive Rapid Diagnostics for Respiratory Diseases in Children**
- **049 Phage -based Diagnostic Platforms for Rapid Detection of Bacterial Pathogens**





040 **Effective Targeted Delivery of RNA-based Vaccines and Therapeutics**

Primary Goal: Develop improved platform technologies for the delivery of RNA into specific cells and tissues to improve the efficacy of HIV vaccines or therapeutics.

- Short-term Goal: Perform feasibility studies for the development and use of delivery mechanisms for RNA-based HIV vaccines and therapies.
- Long-term Goal: Enable a small business to bring fully developed delivery systems for RNA -based HIV vaccines and therapies to the clinic and eventually to the market.



041 Simplified Sequencing for TB Drug Resistance Testing

Goal: Develop low-cost, easy-to-use platform for TB drug resistance testing and surveillance for settings with high HIV prevalence and limited information technology and laboratory resources.

- Platform must rapidly and accurately generate sequence data from smear negative sputum to enable the prediction of resistance to all first and second-line anti-TB drugs.
- Platform must perform highly accurate analysis of the sequence data to produce clinically actionable resistance reports.





042 **Qualitative HIV RNA Home Test**

Goal: Develop method for HIV RNA home-testing.

- Method need not be quantitative, but must meet specific criteria for sensitivity.
- Method must include suitable procedure for obtaining finger stick blood.
- Small handheld units with individual test strips or cartridges are acceptable, but device free, disposable units are preferred.
- Units may require refrigeration, but stability at room temperature is preferable.
- All necessary materials should be supplied with the test.
- Handling required by operator should be suitable for home testing by untrained individuals.





043 **Adjuvant Development**

Goal:

- Accelerate pre-clinical development and optimization of single lead adjuvant candidate or select combination-adjuvant for prevention of human disease caused by non-HIV infectious pathogens.
- Adjuvant must be studied and further developed toward human licensure with currently licensed or new investigational vaccines, and may not be developed as stand-alone agents.

044 **Vaccine Adjuvant Screening and Discovery**

Goal:

- Screening for new adjuvant candidates, their characterization and early-stage optimization.





045 **Database Resources Integration**

Goal:

Support development of a data retrieval and discovery system for integrated access to DAIT-funded bioinformatics resource for data query, knowledge dissemination and integrative analyses.



046 **Rapid Point-of-Care Diagnostics to Detect Serologic Status of Individuals for Select Viral Infections**

Goal: Develop rapid POC diagnostic tests that can determine whether a person has pre-existing antibody to HSV or CMV as an indicator of prior infection.

- Final product should be self-contained.
- Product should require only a small blood sample (e.g., from finger stick).
- Product should provide immediate (less than 30 minute) readout.
- Product should demonstrate the necessary sensitivity and specificity to allow screening of clinical trial subjects/patients for prior virus infection.





047 Development of Microbiome-based Products for Infectious Diseases

Applicants: Small businesses with existing microbiome-based product (live microorganisms, such as bacteria) intended for the treatment or prevention of infectious diseases.

Goal: Further product development by focusing on preclinical studies.

- Applicants are encouraged to focus on IND-enabling studies to support characterization, manufacture and release using product-specific assays.
- Focus should be on characterizing product *re*: identity, genetic stability, purity, potency, transference of genetic material, and mechanism(s) of action.
- New methods to set appropriate specifications are also needed. In addition, novel methods to manufacture complex microbial ecosystems and raw materials are encouraged.
- Novel formulations such as spray drying, lyophilization, and packaging of microbiome-based products for long-term stability are encouraged.





048 Non-Invasive Rapid Diagnostics for Respiratory Diseases in Children

Goal: Develop rapid, sensitive diagnostics for lower respiratory tract infections (bacterial, viral, and/or fungal origin) suitable for children and which utilize non-invasive specimen collection methods.

- Examples of non-invasive specimen types: analytes in exhaled breath, saliva, oral swabs, and bodily secretions (urine, tears, and sweat).
- Proposed diagnostic device (and associated components) should be:
 - simple to use,
 - compatible with POC-use by healthcare personnel,
 - employ reagents that can be stored under ambient conditions,
 - be compatible with U.S. regulatory guidelines for testing and validation.





049 **Phage -based Diagnostic Platforms for Rapid Detection of Bacterial Pathogens**

Goal: Leverage bacteriophages or their relevant biochemical components as tools for development of rapid diagnostic platforms to detect bacterial pathogens that cause serious infections in humans.

- Proposals must address bacteria recently classified by the CDC as antibiotic resistance threats.
- Because drug resistance is key to the threat posed by these pathogens, bacteriophage-based diagnostic platforms that can both identify the pathogens, as well as provide an assessment of antibiotic susceptibility, are preferred.





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Questions?

Charles H. Jackson, Jr.

Contracting Officer

Office of Acquisitions, DEA

National Institute of Allergy and Infectious Diseases

National Institutes of Health, DHHS

Phone: (240) 669-5175

Email: Charles.Jackson@nih.gov





NIDA Topic

>>See NIDA topic in Section 12

Topic #	Ph I?	Fast track?	Direct to Phase II?	Topic Title
NIH/NIDA 161	Yes	No	No	Virtual Reality Tools to Enhance Evidence Based Treatment of Substance Use Disorders
NIH/NIDA 162	Yes	Yes	Yes	Analytical Tools and Approaches for (Multidimensional) Scholarly Research Assessment and Decision Support in the Biomedical Enterprise

Questions?

Andrew Hotaling

Contracting Officer, NIDA R&D Contracts Management

Branch Neurosciences Offices of Acquisition

Phone: (301) 443-6677

Fax: (301) 443-7595

E-mail: hotalingar@mail.nih.gov



Centers for Disease Control and Prevention

SBIR PHS 2017-1 Contract Topics For HHS Pre-Proposal Webinar

Presented by

Sean David Griffiths, M.P.H.

Small Business Innovation Research (SBIR) Program Manager

Office of Technology and Innovation

Office of the Associate Director for Science

August 24, 2016



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CDC SBIR Program

- CDC's Office of the Associate Director for Science (OADS) manages the SBIR Program and works with CDC's Centers, Institutes and Offices to make determinations as to where SBIR funds would best be used to support high quality, high impact SBIR projects that will be of overall benefit to public health
- CDC participates in the SBIR PHS omnibus grant and contract solicitations
 - CDC does not participate in the STTR Program (at this time)
 - CDC has opted to participate in the Majority VC ownership authority (FY15)
- Budget - CDC SBIR set-aside approx \$9.0 million (FY16)



CDC SBIR Program

- Uniqueness of CDC's SBIR Program – life sciences; public health; emergency response – domestic & international
- Awards - ≈ 25 Phase I's up to \$150,000 each and ≈ 5-6 Phase II's per year up to \$1.0 M each
- Grants vs. Contracts –
 - FY13 – 58% grants & 42% contracts
 - FY14 – 25% grants & 75% contracts
 - FY15 – 30% grants & 70% contracts



CDC Strategic Priorities

- Strengthen surveillance, epidemiology, and laboratory services;
- Improve the ability to support state, tribal, local and territorial public health;
- Improve global health impact;
- Increase policy impact; and,
- Better prevent illness, injury, disability and death.



Key Winnable Public Health Battles for the United States

Tobacco



Nutrition, Physical Activity, Obesity and Food Safety

Healthcare-Associated Infections



Motor Vehicle Injuries

Teen Pregnancy



HIV

Where CDC's SBIR Program Intersects with Small Business Concerns/VCs/Entrepreneurs

- Help CDC as we confront the many public health challenges before us:
 - CDC supports groundbreaking health and medical research and real-time emergency response activities to keep the U.S. safe, healthy, and secure;
 - CDC will promote and fund research and development that supports the mission and/or strategic priorities;
 - CDC has roles at the local, state, federal and global levels; and
 - The SBIR program is a way for innovators and entrepreneurs to contribute to making not only the U.S., but the world a healthier and safer place.



CDC/CDC/National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (014) - Multiplexed Digital Counting of Single Molecules for Advanced Molecular Diagnosis

- Number of anticipated awards 2
 - Budget: Phase I up to \$ 150,000 for up to 6 months
- Project goal(s):
 - The goals of the proposed research are to rapidly, simultaneously, and cost-effectively detect and accurately quantify multiple antigen (protein, carbohydrate) and nucleic acid (DNA, RNA) target molecules used in the primary diagnosis of vector-borne infectious diseases caused by viruses, bacteria, and parasites. The technology should ultimately incorporate innovations which enable large numbers of clinical samples and pools of vectors to be analyzed.
- Phase I Activities and Deliverables / Specific project goal(s):
 - Develop assays suitable for use with pools of different vectors and obtain quantitative data from assays.
 - Develop assays suitable for use with clinical samples obtained from different vector-borne diseases and obtain quantitative data from assays.
 - Expand the range of assays available and move toward commercialization of a subset of those assays.



CDC/National Center for Chronic Diseases Prevention and Health Promotion (NCCDPHP) – (038) Improve Contextual Awareness using Social Network Data

- Number of anticipated awards 2
 - Budget: Phase I up to \$ 150,000 for up to 6 months
- Project goal(s):
 - CDC seeks to support the development of an analytics platform that harnesses web/social network data & delivers novel surveillance capabilities for chronic disease indicators. The proposal seeks to build large nationally representative cohorts of social network users for each indicator by unique key characteristics that are systematically inferred from user profiles, tweets, posts, & search behaviors.
- Phase I Activities and Deliverables
 - Conduct a review of the data access & use policy of Twitter, Facebook and other social media
 - Conduct a preliminary study to determine applicable social network data streams & public health indicators
 - Identify appropriate informatics solutions (e.g., natural language processing algorithms) to access, monitor, & extract data
 - Develop a prototype analytics platform with “Cohort builder” function & demonstrate the creation of least one nationally representative cohort in the chronic disease domain





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E-mail: cdcinfo@cdc.gov

Web: www.cdc.gov



Small Business Innovation Research (SBIR)
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Deadline for receipt of ALL Proposals

FRIDAY October 21, 2016

5:00 PM Eastern Daylight Time

Electronic submission must be complete.

No paper submissions.





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